UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

SENEA COYNE, *Plaintiff*	§	
v.	§	**No. 1:21-CV-00086-DAE**
COLOPLAST CORP., *Defendant*	§	

ORDER

Before the Court are Defendant Coloplast Corp.'s Motions to Exclude Testimony and Opinions of Plaintiff's Experts Neeraj Kohli, M.D., M.B.A., Dkt. 48; Jimmy Mays, Ph.D., Dkt. 49; Peggy Pence, Ph.D., Dkt. 50; and Bruce Rosenzweig, M.D., Dkt. 52. The District Judge referred the motions to the undersigned for disposition. The undersigned set the motions for hearing, Dkts. 63, 75, and after considering the parties' filings, the arguments made at the hearing, and the applicable law, the Court announced its rulings on the motions, and the reasons for those rulings, on the record. This written order memorializes those rulings.

I. BACKGROUND

Plaintiff Senea Coyne asserts negligence and product-liability claims against Defendant Coloplast Corp. in connection with injuries she alleges she suffered several years after implantation of Coloplast's Aris product, a polypropylene pelvic mesh product intended to treat Coyne's stress urinary incontinence ("SUI"). Dkt. 13. Coyne asserts that 11 years after her surgeon implanted the device, she began to suffer ongoing bleeding, urinary issues, and problems with intercourse that eventually led

her to have the mesh removed and replaced with a different mesh product. *Id.* Among other causes, Coyne alleges that Coloplast failed to apprise her and her surgeon of the risks the Aris product posed and defectively designed the Aris product. *Id.*

Each of Coyne's challenged experts will offer testimony and expert opinions in support of these claims. Dr. Kohli is a urogynecologist who will testify regarding general and case-specific medical causation. Dkt. 48, at 1. Dr. Mays is a chemical and biomedical engineer with experience in the field of polymer chemistry and polymer biomaterials—including polypropylene, which makes up the Aris product—and will offer his opinions regarding potential material degradation issues inherent in the Aris product. Dkt. 54, at 1-2. Plaintiff intends to call Dr. Pence as an expert on the relevant regulatory landscape. Dkt. 50, at 1. And Dr. Rosenzweig will build on Dr. Mays's degradation opinions and discuss safer alternative designs to the Aris product. Dkt. 52, at 1-3.

As set out in both sides' briefing, each of these witnesses has testified in numerous pelvic-mesh cases around the country. And each has been subjected to similar *Daubert* challenges in those cases. Those courts have excluded some of the proposed testimony and admitted other portions, and the courts have occasionally reached different conclusions regarding which opinions are admissible and which are not. Coyne acknowledges that some of Coloplast's concerns are well-founded and has thus made concessions, noted in the rulings below, that her experts will not opine on certain topics. As for the remaining disputes, the parameters set out in the rulings below are intended to ensure that the testimony and opinions offered at trial meet

the reliability and relevance threshold set by Federal Rule of Evidence 702, without inappropriately infringing on the province of the jury to weigh the competing admissible expert opinions.

II. LEGAL STANDARD

The Supreme Court acknowledged in *Daubert v. Merrell Dow Pharmaceuticals* that Federal Rule of Evidence 702 is the proper standard for determining the admissibility of expert testimony. 509 U.S. 579, 597-98 (1993). Under *Daubert* and Rule 702, the district court must act as a "gatekeeper" by ensuring that an expert's testimony rests on a reliable foundation. *Id.*; Fed. R. Evid. 702. Courts must admit expert testimony if (1) the expert is qualified; (2) the evidence is relevant to the litigation; and (3) the evidence is reliable. *Orthoflex, Inc. v. ThermoTek, Inc.*, 986 F. Supp. 2d 776, 782 (N.D. Tex. Nov. 20, 2013). *Daubert* and its principles apply to both scientific and non-scientific expert testimony. *Kumho Tire v. Carmichael*, 526 U.S. 137, 147 (1999).

Experts need not be highly qualified to testify; nonetheless, courts need not admit testimony that is based purely on the unsupported assertions of the expert. *Gen. Elec. Co. v. Joinder*, 522 U.S. 136, 146 (1997); *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 276 (5th Cir. 1998). The focus of the reliability inquiry is on the principles and methodology an expert uses in forming her opinions rather than the expert's conclusions. But in conducting the reliability analysis, the Court must also consider whether, for a given conclusion, "there is simply too great an analytical gap between the data and the opinion proffered." *General Electric Co. v. Joiner*, 522 U.S. 136, 146

(1997). The party proffering expert testimony has the burden of establishing that the challenged testimony is admissible. Fed. R. Evid. 104(a).

III. ORDER

For the reasons stated on the record, the Court **DENIES** Coloplast's motion to exclude testimony from Dr. Kohli, Dkt. 48; **GRANTS IN PART and DENIES IN PART** Coloplast's motion to exclude testimony from Dr. Mays, Dkt. 49; **GRANTS** Coloplast's motion to exclude testimony from Dr. Pence, Dkt. 50; and **GRANTS IN PART and DENIES IN PART** Coloplast's motion to exclude testimony from Dr. Rosenzweig, as set forth the below:

A. Neeraj Kohli, M.D., M.B.A., Dkt. 48

The Court **DENIES** Coloplast's motion to exclude testimony from Dr. Kohli.

B. Jimmy Mays, Ph.D., Dkt. 49

Plaintiff agrees that Dr. Mays will not testify as to several topics. Accordingly, the Court **GRANTS** Coloplast's motion to exclude testimony from Dr. Mays regarding (1) medical complications associated with polypropylene mesh; (2) safer alternative designs; (3) toxicology (but the material safety data sheets are a reliable basis for his degradation opinions); and (4) Coloplast's mental state or corporate intent.

The Court **DENIES** Coloplast's motion in all other respects.

C. Peggy Pence, Ph.D., Dkt. 50

The Court **GRANTS** Coloplast's motion to exclude testimony from Dr. Pence.

D. Bruce Rosenzweig, M.D., Dkt. 52

Plaintiff agrees that Dr. Rosenzweig will not testify as to several topics. Accordingly, the Court **GRANTS** Coloplast's motion to exclude testimony from Dr.

Rosenzweig regarding (1) the "Burch" procedure; (2) Aris's lack of a sheath; (3) the nature of the testing Coloplast should have performed. As to the last point regarding testing, the Court further **GRANTS** Coloplast's motion to exclude testimony from Dr. Rosenzweig regarding what testing Coloplast did and did not perform, and to describe what information was or was not available as a result of that testing (or lack thereof), as detailed in his report.

In addition, the Court **GRANTS** Coloplast's motion to exclude Dr. Rosenzweig's safer-alternative-design opinions regarding the autologous fascia sling and biologic allograft sling products.

The Court **DENIES** Coloplast's motion in all other respects.

SIGNED January 17, 2024.

DUSTIN M. HOWELL
UNITED STATES MAGISTRATE JUDGE